THE LAWYERING PROJECT

99 Silver Street, 4-10
Portland, ME 04101

Rupali Sharma
Direct Line: 908.930.6645
rsharma@lawyeringproject.org

January 16, 2019

Kristina Box, MD, FACOG
State Health Commissioner
Indiana State Department of Health
2 North Meridian Street
Indianapolis, Indiana 46204

Dear Dr. Box:

On behalf of Whole Woman's Health Alliance ("WWHA"), enclosed please find an Application for a License to Operate an Abortion Clinic and the following supporting documents:

- Certificate of Authority from the Office of the Secretary of State of Indiana,
- a written agreement and confirmation of privileges satisfying Ind. Code § 16-34-2-4.5(a)(2),
- a supplement providing the disclosures required by Ind. Code § 16-21-2-11(d),
- a request for a waiver from rules relevant only to surgical abortion,
- a check in the amount of $500 payable to the Indiana State Department of Health ("Department"), and
- all inspection reports and violation remediation contracts concerning WWHA's Texas and Virginia clinics.

Given the Department's past interest in WWHA's ownership structure, WWHA also offers the following information:

WWHA is a nonprofit organization incorporated in Texas. As a nonprofit, it has no owners or members. Rather, it is fully controlled by a nine-member Board of Directors.

WWHA operates two abortion clinics, one at 8401 North IH 35, Suite 200, Austin, Texas 78753, and the other at 2321 Commonwealth Drive, Charlottesville, Virginia 22901. The clinics are licensed by Texas and Virginia, respectively and accredited by the National Abortion Federation ("NAF").

WWHA has contracted with Whole Woman's Health, LLC, ("WWH LLC") a healthcare management company, to receive human resources, financial, marketing, and other services. WWH LLC serves as an independent contractor to WWHA under this agreement.

WWH LLC also provides healthcare management services to the following clinics, which have no legal or financial relationship with WWHA:

- Whole Woman's Health of McAllen, LLC, located at 802 South Main Street, McAllen, Texas 78501, and accredited by NAF;
- Whole Woman's Health of Fort Worth, LLC, located at 3256 Lackland Road, Fort Worth, Texas 76116, and accredited by NAF;
- Whole Woman's Health of Baltimore, LLC, located at 7648 Belair Road, Baltimore, Maryland 21236, and accredited by NAF;
- Whole Woman's Health of the Twin Cities, LLC, located at 825 South 8th Street, Suite 1018, Minneapolis, Minnesota 55404, and accredited by NAF;
- Whole Woman's Health of Peoria, LLC, located at 7405 North University Street, Peoria, Illinois 61614, and accredited by NAF; and
- Whole Woman's Health of San Antonio, LLC, ("WWH of San Antonio") located at 4025 East Southcross Boulevard, Building 5, Suite 30, San Antonio, Texas 78222, and accredited by NAF.

WWH LLC, and every clinic listed above except WWH of San Antonio, is fully owned by The Booyah Group, LLC, ("Booyah") a holding company. Booyah, in turn, is owned by Amy Hagstrom Miller, who also serves as President and CEO of WWHA. WWH of San Antonio is only partly owned by Booyah and partly owned by a private investor.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Rupali Sharma
Senior Counsel & Director

encs.
cc: Sharon Lau
Amy Hagstrom Miller
Katherine D. Jack
Dipti Singh
Stephanie Toti

APPLICATION FOR LICENSE TO OPERATE AN ABORTION CLINIC

State Form 52238 (R5 / 9-18)
Indiana State Department of Health-Division of Acute Care
(Pursuant to IC 16-21-2 and 410 IAC 26)

RECEIVED
JAN 25 2019

Division of Acute Care Use Only

Date Received *(mm/dd/yyyy)*_____ Date Approved *(mm/dd/yyyy)*_____ Date Rejected *(mm/dd/yyyy)*_____

Please Type or Print Legibly.

SECTION I - TYPE OF APPLICATION

Application *(Check appropriate item.)*

☑ New Facility ☐ Renewal ☐ Change of Ownership *(Anticipated date of Sale/Purchase/Lease (mm/dd/yyyy))* _____
Submit a dated and signed copy of the bill of sale, lease or other document of transfer.

SECTION II - IDENTIFYING INFORMATION

A. Abortion Clinic Location

Name of Abortion Clinic
Whole Woman's Health Alliance

Street Address *(number and street)*	P.O. Box
3511 Lincoln Way West	

City	County	ZIP Code +4
South Bend	St. Joseph	46628-1411

Telephone Number	Fax Number
( )	( )

Abortion Clinic e-mail address: _____

Internet Web Address: https://www.wholewomanshealthalliance.org/

B. Mailing Address *(If different from abortion clinic location)*

Street Address *(number and street)*	P.O. Box

City	County	ZIP Code +4

C. Licensee / Ownership Information

Licensee: The applicant entity as registered with the secretary of state
Whole Woman's Health Alliance

Street Address *(number and street)*	P.O. Box
1812 Centre Creek Drive, Suite 205	

City	State	ZIP Code +4
Austin	Texas	78754

Telephone Number	Fax Number	EIN Number	Fiscal Year End Date *(mm/dd)*
(512) 835-6858	(512) 835-6568	46-5318393	12/31

D. Services provided under this license:

Code items 1 and 2 as follows: 1. Provided directly by employee(s), 2. Provided by a contract service, 3. Both 1 and 2.

1. Ancillary Services: ☐ Laboratory; CLIA Certificate Number _____ ☐ Radiology ☐ 1 Counseling

☐ 1 Family Planning ☐ Pharmacy ☐ Other *(List)*: _____

2. Surgical Services: ☐ Gynecology ☐ Other *(List)*: _____

For Item 3; indicate the total number of individuals (employees plus contractors) working in this clinic. This includes hourly, part-time, and full-time persons.

3. Staffing: Physicians: ☐ 1 Registered Nurses: ☐ Licensed Practical Nurses: ☐

Licensed Social Workers: ☐ Other *(List title and number)*: APC 1

E. Number of Procedure Rooms Utilizing:

Local analgesia / anesthetic ☐ 0 Moderate / Conscious Sedation ☐ 0

F. Type of Entity:

For Profit	Non-Profit	Government
☐ Individual	☐ Church Related	☐ State
☐ Partnership	☐ Individual	☐ County
☐ Corporation	☐ Partnership	☐ City
☐ Limited Liability Company	☑ Corporation	☐ City/County
☐ Sole Proprietorship	☐ Limited Liability Company	☐ Hospital District
☐ Other *(specify)* _____	☐ Other *(specify)* _____	☐ Federal
		☐ Other *(specify)* _____

G. Officers *(If the business entity is incorporated)*

Position	Name	Address/City/State/ZIP
President / Chairperson / CEO	Amy Hagstrom Miller	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754
Vice-President / Vice-Chairperson / COO	Beverly Whipple	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754
Treasurer / CFO	Beverly Whipple	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754
Secretary	John H. Bucy, II	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754

H. Ownership and/or Change in Ownership:

List names and addresses of individuals or organizations having direct or indirect ownership or controlling interest of five percent (5%) in the applicant entity. Indirect ownership interest is an entity that has an ownership interest in the applicant entity. Ownership in any entity higher in a pyramid than the applicant constitutes indirect ownership. *(Use additional sheet if necessary.)*

Name	Business Address/City/State/ZIP	EIN Number

CERTIFICATION OF APPLICATION

The undersigned hereby makes application for a license to operate an Abortion Clinic (Clinic) in the State of Indiana, and in support of this application, represents and shows that the owner(s) and operator(s) are of reputable and reasonable character, are able to comply with the Abortion Clinic statutes, IC 16-21-2-2.5 and IC 16-34, and the rules promulgated there under, 410 IAC 26 and will operate and maintain this clinic in accordance with those rules.

I certify that the operational policies of the clinic will not provide for discrimination based upon race, color, creed, or national origin.

I swear and affirm under the penalty of perjury that all statements made in this application and any attachments thereto are correct and complete and that I will comply with all regulations, laws, and rules governing the licensing of clinics in Indiana.

Signature of the Medical Director:	Jeffrey D. Glazer M.D.
Printed Name and Title:	Jeffrey D. Glazer, M.D.
Date of Signature *(mm/dd/yyyy)*:	01/15/2019
Signature of the Clinic Administrator:	
Printed Name and Title:	Sharon Lau, Midwest Advocacy Director, Whole Woman's Health Alliance
Date of Signature *(mm/dd/yyyy)*:	1-16-19

See the following page for instructions regarding licensure fees and submission of this application.

License Fee

Select the appropriate fee based upon the total number of first trimester procedures as reported to the Indiana State Department of Health (ISDH) on the Terminated Pregnancy Report (State Form 36526).

Check One	Total First Trimester Procedures in the Clinic	Fee
✓	Zero to 799	$500.00
	800 to 3,499	$1,000.00
	3,500 to 6,999	$2,000.00
	7,000 and above	$3,000.00

Abortion Clinic License Fees; 410 IAC 15-5-3

Enclose the following:

1. A completed Application for License to Operate an Abortion Clinic (this form).

2. Any supporting attachments.

3. For each physician performing procedures, either:

(A) A copy (in writing) of the physician's admitting privileges; or
(B) A copy of:
(1) his/her written agreement with another physician with admitting privileges; and
(2) a copy (in writing) of that physician's admitting privileges.

4. Payment made payable to "Indiana State Department of Health."

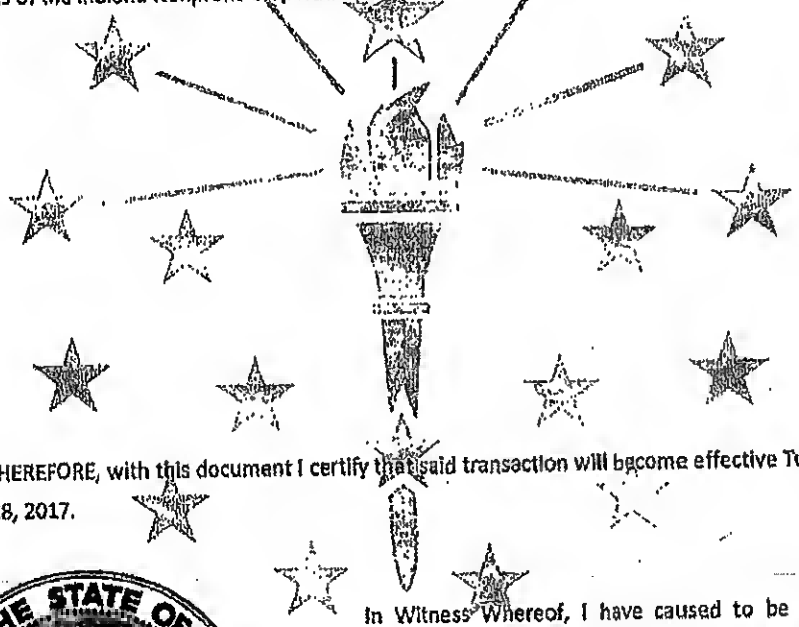
Mail to:

INDIANA STATE DEPARTMENT OF HEALTH
ATTENTION: CASHIER'S OFFICE
2 NORTH MERIDIAN STREET, SUITE 2-C
INDIANAPOLIS, INDIANA 46204

State of Indiana
Office of the Secretary of State

Certificate of Authority
of
WHOLE WOMAN'S HEALTH ALLIANCE, INC.

I, CONNIE LAWSON, Secretary of State, hereby certify that an Application for Certificate of Authority of the above Foreign Nonprofit Corporation has been presented to me at my office, accompanied by the fees prescribed by law and that the documentation presented conforms to law as prescribed by the provisions of the Indiana Nonprofit Corporation Act of 1991.



NOW, THEREFORE, with this document I certify that said transaction will become effective Tuesday, March 28, 2017.

In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, March 29, 2017

Connie Lawson

CONNIE LAWSON
SECRETARY OF STATE

201703281188179 / 7561392

To ensure the certificate's validity, go to https://bsd.sos.in.gov/PublicBusinessSearch

Whole Woman's Health Alliance
Whole Woman's Health of South Bend
9821 Lincoln Way West
South Bend, IN 46618

Emergency Services Agreement

This agreement between and offers medical transfer services for Whole Woman's Health of South Bend in accordance with Ind. Code Ann. §16-34-2-4.8.

agrees to accept referrals from for patients who may require evaluation, treatment, or follow up care from any complications from services provided at Whole Woman's Health of South Bend. affirms that currently has privileges at a hospital in St. Joseph's County or a county contiguous thereto.

07-25-17
Date

J.E. 3

Whole Woman's Health Alliance

Whole Woman's Health of South Bend

3511 Lincoln Way West

South Bend, IN 46628

Emergency Services Agreement

This agreement between and , offers medical transfer services for Whole Woman's Health of South Bend in accordance with Ind. Code Ann. Section 16-34-2-4.5.

agrees to accept referrals from for patients who may require evaluation, treatment, or follow up care from any complications from services provided at Whole Woman's Health of South Bend. affirms that she currently has privileges at a hospital in St. Josephs' County or a county contiguous thereto.

12-18-18

Date

Supplement to WWHA's Application for a License to Operate an Abortion Clinic

Pursuant to Ind. Code § 16-21-2-11(d)(1), Whole Woman's Health Alliance ("WWHA") hereby discloses that it has never operated an abortion clinic that was closed as a direct result of patient health and safety concerns. WWHA does not have any owners or affiliates. In the past, the Department has erroneously contended that the following abortion clinics are or were affiliates of WWHA:

- Whole Woman's Health of Austin, LLC
- Whole Woman's Health of McAllen, LLC
- Whole Woman's Health of San Antonio, LLC
- Whole Woman's Health of Fort Worth, LLC
- Whole Woman's Health of the Twin Cities, LLC
- Whole Woman's Health of Peoria, LLC
- Whole Woman's Health of Beaumont, LLC
- Whole Woman's Health of Baltimore, LLC

Although these clinics are wholly independent of WWHA, WWHA has ascertained from their owner, Amy Hagstrom Miller, that none of them was closed as a direct result of patient health and safety concerns.

Pursuant to Ind. Code § 16-21-2-11(d)(2), WWHA hereby discloses that none of its Board members or clinic staff members has ever been convicted of a felony. WWHA does not have a principal; it is controlled by a nine-member Board of Directors

Pursuant to Ind. Code § 16-21-2-11(d)(3), WWHA hereby discloses that none of its Board members or clinic staff members has ever been employed by a facility owned or operated by WWHA that closed as a result of administrative or legal action. WWHA does not have a principal; it is controlled by a nine-member Board of Directors

Dated: January 16, 2019

Sharon Lau
Clinic Administrator
Midwest Advocacy Director,
Whole Woman's Health
Alliance

THE LAWYERING PROJECT

99 Silver Street, 4-10
Portland, ME 04101

Rupali Sharma
Direct Line: 908.930.6645
rsharma@lawyeringproject.org

January 16, 2019

Kristina Box, MD, FACOG
State Health Commissioner
Indiana State Department of Health
2 North Meridian Street
Indianapolis, Indiana 46204

Dear Dr. Box:

Whole Woman's Health Alliance ("WWHA"), a Texas nonprofit organization, is submitting an abortion clinic licensing application to the Indiana State Department of Health for a clinic to be located at 3511 Lincoln Way West, South Bend, Indiana. Our clinic at 3511 Lincoln Way West will not provide surgical abortions; rather, it will only offer patients the option of a non-surgical (medication) abortion using the medications, mifepristone and misoprostol.

Ind. Code § 16-21-1-9 states that the State Health Commissioner may waive a rule for good cause shown, and if the waiver "will not adversely affect or increase any risk to the health, safety, or welfare of existing or potential residents or patients." In connection therewith, and pursuant to § 16-21-1-9, WWHA requests a waiver of the abortion licensing requirements itemized below; we respectfully submit that the waiver should be granted, as it will not adversely affect or increase any risk to the health, safety, or welfare of existing or potential residents or patients. We also respectfully note that Planned Parenthood of Indiana and Kentucky has previously received a waiver of each of the requirements listed below from the State Health Commissioner for its clinic in Lafayette, based on the same rationales explained below.

As stated above, we will offer only non-surgical (medication) abortions, in compliance with all applicable Indiana laws. Because no surgery or procedure is performed in connection with a medication abortion, the waiver of the rules itemized below will not adversely affect or increase any risk to the health, safety, or welfare of our patients.

We respectfully request that the State Health Commissioner waive the following rules:

RULE	RATIONALE
410 IAC 26-10-1(b)(5): Observation During Recovery Period	There is no recovery period necessary in the provision of a non-surgical abortion since there is no surgery from which to recover.
410 IAC 26-11-2(a): Sterilization of Equipment and Supplies	Non-surgical abortions will be performed by medication, not surgery; no sterile equipment or supplies are required in order to give patients an oral medication.
410 IAC 26-11-3: Laundry	The clinic will use disposable linens and therefore there is no need for the laundry processing requirements to apply.
410 IAC 26-13-1: Anesthesia	No anesthesia is used and therefore there is no need for the listed anesthesia services.
410 IAC 26-13-3(b), (c): Anesthesia and Surgical Services, Emergency Equipment and Supplies	There is no procedure performed and no procedure room; there is no recovery needed and no recovery room. Therefore, there is no need for the itemized emergency supplies.

RULE	RATIONALE
410 IAC 26-17-2(c)(3): Toilet Room	The clinic does not have a separate restroom (toilet and hand washing station) in the waiting room. However, there is a patient restroom (toilet and hand washing station) that will also be available to visitors in the waiting room.
410 IAC 26-17-2(c)(4): Drinking Fountain	The clinic does not have a water fountain. However, we will provide a water cooler and/or bottled water to patients and visitors.
410 IAC 26-17-2(d)(1): Physical Plant Standards: Procedure Room Size and Traffic Flow	As noted above, there is no procedure performed and no procedure room used for a non-surgical abortion. Medications may be dispensed in an examination room, which may be less than 120 square feet. There is no need for procedure rooms to be segregated/removal from traffic flow, as there are no such rooms.
410 IAC 26-17-2(d)(2): Hand Washing Station in Procedure Room	As noted above, there are no procedure rooms. Hand washing stations are available in the patient restroom.

RULE	RATIONALE
410 IAC 26-17-2(d)(3): Scrub Facilities	As noted above, there are no procedures performed for non-surgical abortions, and no procedure rooms. Therefore, scrub facilities are not required near procedure rooms.
410 IAC 26-17-2(d)(4): Recovery Areas/Rooms	As noted above, there is no procedure performed in a non-surgical abortion and therefore no need for a recovery area or recovery rooms.
410 IAC 26-17-2(d)(6): Toilets	As described above, there is a patient restroom (toilet and hand washing facilities) in the clinic area, available for use by patients as well as visitors in the waiting area.

We appreciate your timely consideration of our request, and we await your response. If you have any questions, please do not hesitate to contact me at (908) 930-6645 or rsharma@lawyeringproject.org.

Sincerely,

Rupali Sharma
Senior Counsel & Director

encs.

cc: Sharon Lau
Amy Hagstrom Miller
Katherine D. Jack
Dipti Singh
Stephanie Toti

Whole Woman's Health Alliance

August 2, 2017

TO: Tonia Thomas, Administrative Assistant IV
Patient Quality Care Unit
Health Facility Compliance Group-Austin

FR: Whole Woman's Health Alliance – DSHS Lic# 140013
, Director of Clinical Services

RE: Plan of Correction
DSHS Survey Inspection

Whole Woman's Health Alliance's mission is to raise the standard of care in our communities, and to achieve this goal we have developed strict customer service and infection control policies that guarantee patient satisfaction and safety.

We want to assure the Department, Whole Woman's Health Alliance complies with all Abortion Facility Regulations, as well as our own high standards for customer service and satisfaction. Three out of the four deficiencies cited during the survey conducted on 07/24/17 were due strictly to clerical errors in documentation, that did not jeopardize patient safety in any way, and the fourth deficiency was related to our flexibility to meet our patient's requests for a schedule that would work with them.

Our commitment to excellent patient centered care continues to be our priority, and we are taking the necessary measures to ensure proper documentation and strict adherence to policies and procedures is accurately followed.

Attached you will find a Plan of Correction for the deficiencies cited during the survey conducted on July 24th, 2017

Please reach us with questions at any time by calling our corporate office at 512-835-6858

Respectfully,

Director of Clinical Services
Whole Woman's Health Alliance

8401 North IH 35, Suite 200
Austin, TX 78753

TX Department of Aging and Disability Services
Regulatory Services

STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

RECEIVED
JAN 25 2018

Form OAOS 3724
July 2015

PRINTED: 07/26/2017 1:50:31PM

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	TAC 139 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An entrance conference was held with the Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions. Initial licensure is recommended, with an approved plan of correction. An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the afternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000		
A 126	TAC 139.41(a) Policy Development and Review (a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:	A 126		

SOD - State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: _____ TITLE: Director of Clinical Services (X6) DATE: 08/04/2017

H7XF11

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	6401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 126	Continued From page 1 This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment. Findings were: During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9). In an interview with staff members #6 & #7, neither member was able to explain the 1 ml Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17. According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule (I/IIN Controlled Substances (2/2N) Substances in this schedule have a high potential for abuse which may lead to severe psychological	A 126	A 126 The Clinic Manager is responsible for ensuring compliance with all policies governing the facility operations. Whole Woman's Health Alliance (WWHA) complies with the policy and review requirement for abortion facilities by developing and following The WWHA Medication Therapy Practices. The error identified by the surveyors was related to a clerical miscount, and not to any missing doses. The Clinic Manager conducted and audit of the controlled substances during the survey, and found the miscount error which was immediately corrected. A staff in-service was facilitated on 7/24/17 in order to train staff on how to properly count, document the medications, and to reinforce understanding of the existing Medication Therapy Practices policy. In our order to monitor compliance, in addition to the daily open and close counts, a monthly audit of the control substances log will be conducted by the Clinical Coordinator and reviewed by the Clinic Manager.	07/24/17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 126	Continued From page 2 or physical dependence. Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone. Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital." Facility policy titled "Medication Therapy Practices" stated, in part: "Controlled Medications Closing Count" 1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication log. ... 8. Any discrepencies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report. Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review." The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17.	A 126		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 257	Continued From page 3	A 257		
A 257	TAC 139.49(d)(5)(L)((ii)(I - V) Infection Control Standards (L) Performance records. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) identification of operator(s); This Requirement is not met as evidenced by: Based on a review of performance records and interview, the facility failed to ensure that each sterilizer was monitored during operation for pressure, temperature, and time at desired temperature and pressure, as evidenced by the fact that a record was not maintained that included: duration and temperature of exposure phase (if not provided on sterilizer recording charts). Finding included: Review of the autoclave logs for May, June, and July 2017 revealed that pressure, temperature, and duration of exposure at desired temperature and pressure of the sterilized logs was not documented. In an interview on 07/24/17, staff member #7 stated that the new autoclave forms have an area to document the pressure and temperature,	A 257	A 257 The Clinic Manager is responsible for monitoring proper documentation of infection control standards. Whole Woman's Health Alliance has accurate confirmation that all instruments have been properly sterilized. In addition to the autoclave load logs the facility uses special sterilization pouches, sterilization strips, and sterilization tape that automatically confirms instruments are properly sterile without requiring staff documentation. The autoclave load log in question has been updated to include the pressure, temperature, and time of sterilization process. A staff in-service will be facilitated on 08/09/17 in order to train staff on the updated log and how to properly document. In order to monitor compliance, the Clinical Coordinator will conduct a monthly audit of the logs, any findings needing attention will be presented to the clinic manager to address proper documentation is in place.	08/09/2017

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 257	Continued From page 4 however the facility was utilizing old logs that did not contain a prompt to document this information. The new forms also did not have an area to document duration of the exposure phase. With no documentation of these elements it is unknown if these loads and instruments were effectively sterilized. Facility policy titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" states, in part: "Performance Records Performance records for all sterilizers will be maintained for each cycle. And will be retained for two years.(sic) These records will be available for review within two hours during the specified two-year period. All sterilizers will be monitored during operation for pressure, temperature, and time at desired temperature and pressure. The performance record will include: -Sterilizer identification number -Sterilization date -Sterilization time -Load number -Pack ID#" -Duration and temperature of exposed phase -Identification of operator -Results of biological tests and dates performed -Time/temperature recording charts from each sterilizer" The above findings were confirmed on 07/24/17 in an interview with staff member #7.	A 257		

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A 315	Continued From page 5	A 315		
A 315	House Bill 2 Medical and Clinical Services A physician must provider the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from the abortion or ask health-related questions regarding the abortion; and b) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the physician failed to provide the pregnant women with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. Findings were: During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, #14, #15 and #16) contained no documentation that the patient had been furnished with the name and/or telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. -Patients #2, #3, #4, #5 and #6 had been provided with a hospital name but no telephone number for the hospital. -Patients #12, #13, #14, #15 and #16 had been	A 315	A 315 The Clinic Manager is responsible for ensuring compliance with all policies regarding medical and clinical services. Whole Woman's Health Alliance complies with the requirements set forth in House Bill 2 by providing patients with the written name and phone number of the hospital nearest to them at the time of their discharge from our care. A staff in service will be facilitated on 08/09/17 to re train staff to document this information on the discharge section of the patient's abortion record. In order to monitor compliance, patient charts will be audited at the end of every clinic day, as well as a random monthly chart audit conducted by clinic staff under the supervision of the Clinic Manager.	08/09/17

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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A 315	Continued From page 6 provided with neither a hospital name nor a telephone number for the hospital. The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17.	A 315		
A 327	House Bill 2 Medical and Clinical Services Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug. This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the physician failed to ensure that the patient was scheduled for a follow-up appointment within 14 days. Findings were: Based on the review of 21 clinical records, 1 of 21 (patient #1) was not scheduled to return to the clinic for a follow-up visit within the required 14	A 327		

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A 327	Continued From page 7 days (appointment was scheduled for 21 days after). The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17.	A 327	A327 The Clinic Manager is responsible for ensuring compliance with all medical and clinical services requirements. Whole Woman's Health Alliance had taken a proactive approach to schedule follow up appointments by working with the patient's availability to ensure they could return to the clinic for their follow up. Effective immediately, we will schedule follow up appointments for patients receiving the medical abortion pill to be 14 days without exception. In order to monitor compliance with this requirement the Administrative Coordinator will supervise the patient follow up schedule on a weekly basis. A staff in-service will be facilitated on 08/09/17 in order to ensure staff understanding of this requirement.	08/09/17

Texas Health and Human Services Commission

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	140013	A. BUILDING _____ B. WING _____	10/15/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 000	TAC 139.1 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (b) Scope and applicability. (1) Licensing requirements. (A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements. (B) The following need not be licensed under this chapter: (i) a hospital licensed under Health and Safety Code, Chapter 241; (ii) an ambulatory surgical center licensed	6 000		

SOD - State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Clinic Manager | (X6) DATE: 11/21/2018

STATE FORM 6899 8G8511 If continuation sheet 1 of 19

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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6 000	Continued From page 1 under Health and Safety Code, Chapter 243; or (III) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period. (2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed). Based on observation, the licensee of the abortion facility was not responsible for ensuring the facility's compliance with the Act and this chapter. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise. ... (2) Abortion facility--A place where abortions are performed. (3) Act--Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245. ... (18) Facility--A licensed abortion facility as defined in this section. ... (25) Licensed abortion facility--A place licensed by the department under Health and Safety Code, Chapter 245, where abortions are performed.	6 000		

Texas Health and Human Services Commission

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6 000	Continued From page 2 Findings were: Based on Health and Safety Code, Chapter 245: "Sec. 245.025. HUMAN TRAFFICKING SIGNS REQUIRED. (a) An abortion facility shall display separate signs, in English, Spanish, and any additional language as required by Subsection (b), side by side in accordance with this section in each restroom and patient consulting room. The signs must include the following information: (1) no person, including an individual's parents, may force any individual to have an abortion; (2) it is illegal for a person to force an individual to engage in sexual acts; (3) a woman who needs help may call or text a state or national organization that assists victims of human trafficking and forced abortions; and (4) the toll-free number of an organization described by Subdivision (3). (b) Signs required under this section must be in English and Spanish. If an abortion facility is located in a political subdivision required to provide election materials in a language other than English or Spanish under Section 272.011, Election Code, the facility shall display a separate sign in that language. (c) Signs required under this section must be at least 8-1/2 by 11 inches in size and displayed in a conspicuous manner clearly visible to the public and employees of an abortion facility. The notice must cover at least four-fifths of the sign. (d) The executive commissioner shall adopt rules as necessary to implement and enforce this	6 000	6 000 • The Clinic Manager is responsible for ensuring that human trafficking signs are displayed in each restroom, and patient consulting room. • The Clinic Manager posted the human trafficking signs in English and Spanish in each examination room, restroom, and counseling room on 10/16/2018. • In order to monitor continued compliance, the Clinic Manager will observe the restrooms, patient exam rooms, and counseling rooms monthly to ensure that the human trafficking signs are properly displayed.	10/16/18

Texas Health and Human Services Commission

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	140013	A. BUILDING _____ B. WING _____	10/18/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 209 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 000	Continued From page 3 section. Added by Acts 2017, 85th Leg., R.S., Ch. 858 (H.B. 2552), Sec. 12, eff. September 1, 2017." A tour of the facility on 10/15/18 revealed human trefficking signage was posted in patient bathrooms, but not in patient consultation rooms. The above was confirmed in an interview with staff member #1 on the afternoon of 10/15/18. An entrance conference was conducted on the morning of 10-15-2018 with the Director of Clinical Services. The purpose and process of the re-licensure survey were discussed, and an opportunity was given for facility staff to ask questions. All questions were answered. Continued licensure is recommended with an approved Plan of Correction. An exit conference was conducted on the evening of 10-15-2018 with the Director of Clinical Services. The preliminary findings of the survey were discussed, and an opportunity was given given for facility staff to ask question. All questions were answered.	6 000		
6 023	TAC 139.40 Policy Development and Review (a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide	6 023		

Texas Health and Human Services Commission

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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6 023	Continued From page 4 health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following: (1) administrative policies governing the administration of the facility, covering at a minimum: (A) personnel; (B) employee orientation, training, and evaluation; (C) employee and patient record system; (D) auditing system for monitoring state or federal funds; (E) advertisements for the facility; (F) accuracy of public education information materials and activities in relation to abortion, birth control, and sexually-transmitted diseases; (G) patient education/information services and referral services; (H) reporting requirements; and (I) procedures for the resolution of complaints regarding care or services rendered by licensed health professionals and other members of the facility staff, including contract services or staff. The facility shall document the receipt and the disposition of the complaint. The investigation and documentation shall be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.	6 023		

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6 023	Continued From page 5 (2) clinical policies governing medical and clinical practices and procedures of the facility, covering at a minimum: (A) the provision of medical and clinical services; (B) the provision of laboratory services; (C) examination of fetal tissue; (D) disposition of medical waste; (E) emergency services; (F) condition on discharge procedures; (G) clinical records; (H) reporting and filing requirements; and (I) monitoring post-procedure infection(s). (3) a policy to ensure that the facility is in compliance with fire safety provisions as required by the local codes; (4) policies on decontamination, disinfection, and sterilization, and storage of sterile supplies; (5) policies for parental notice for unemancipated pregnant minors as stipulated in Family Code, Chapter 33; (6) policies for informed consent as stipulated in Health and Safety Code, Chapter 171, the Woman's Right to Know Act;	6 023		

Texas Health and Human Services Commission

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6 023	Continued From page 6 (7) policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261; and (8) policies to ensure all women who present to obtain an abortion provide identification that includes the woman's date of birth. (A) if the woman does not have identification stating her date of birth, she shall be required to execute an affidavit on a form published by the department indicating that she does not have appropriate identification and indicating her date of birth on the affidavit. Attached Graphic (B) The facility shall keep a copy of the identification presented or the affidavit in its files. (b) The licensee, in fulfilling its responsibility under subsection (a) of this section, shall review the facility's written policies and procedures periodically, but no less than once every two years; date to indicate time of last review; revise as necessary; and enforce. This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment. Findings were: During a tour of the facility on 10/15/18, a random count of Midazolam (a Schedule IV controlled)	6 023		

Texas Health and Humen Services Commission

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S 023	Continued From page 7 was performed. 400 ml of Midazolem was present in boxed vials. 4 ml of Midazolem was present in an 2 unopened vials (not in a box). 1 open multi use vial of Midazolam wes observed with markings on the side to count the emount in the vial. The surveyor observed 7 ml of Midezolam in the open via, for a total of 411 ml. The vial had a tebel indicating that 6 ml were counted of Midazolam, for e total of 410 ml of Midazolam. The Midazolam count on 10/16/18 was verified by staff #2, present during the tour and the narcotic count. The nercotic count sheet indicated that 410 ml of had been present during the closing count conducted on 10/15/18 (which had been verified and signed off on by staff #2 end e second staff member). In en interview with steff member #2 they were unable to explain the 1 ml Midazolam discrepancy. According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule IV drug is described as follows: "Schedule IV Controlled Substances Substances in this schedule have a low potential for ebuse reletive to substances in Schedule III. Examples of Schedule IV substences include: elprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midezolam (Vereed®), temezepam (Restoril®), end triazolam (Halcion®). Facility policy titled "Procedure for Hendling Controlled Medications" stated, in part: "Closing Count" 1. Each day that Controlled Medications are administered, at the end of the dey, two staff will open the safe and count eech drug on the	S 023	S 023 • The Clinic Manager is responsible for ensuring that staff members will complete an accurate narcotic count at the opening and closing of each session. • Multi-use vials ere pre-prepared by the manufacturer with a slight overage (approximate 1 cc volume) to account for regular waste when drawing up individual doses. The 1 cc overage is considered to be part of the manufacturers' supplied volume that had not been wasted when drawing up the 4 cc out of the 10 cc vial. • The Clinic Manager will direct the order of single use vials for purchase when available by the manufacturer. • The narcotic count was verified on 10/16/2018 by the Clinic Meneger and the Clinic Coordinator. A narcotic deviation was created for the additional 1cc of Midazolam. The deviation documentation was signed and placed in the nercotic log on 10/16/2018. • The Director of Clinical Services conducted a re-training of Whole Woman's Health Handling Controlled Medications Protocol with the Clinic Meneger, Clinic Coordinator, and all clinical staff on 10/18/2018. Staff are aware to notify Clinic Manager and Medical Directer of any narcotic deviations. • In order to monitor continued compliance, the Clinic Meneger will randomly observe staff open and	10/18/18

			close narcotic count during session for a one month duration. The Clinic Manager will also complete a monthly audit of the narcotic log. This will enable the Clinic Manager will be able to determine whether Controlled Medications policies are being followed.	

Texas Health and Human Services Commission

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	140013	A. BUILDING: _____ B. WING _____	10/16/2018

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6 023	Continued From page 8 Controlled Medication log. ... 7. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report (see sample attached). Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and and Director of Clinical Services included in the Quarterly QA Review... 9. The closing count will be documented in red ink on the Controlled Medication Log." The above was confirmed in an interview with staff #1 and 2 on the afternoon of 10/15/18.	6 023		
6 033	TAC 139.48 Physical and Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; (B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area; (C) have a separate recovery room if moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia are administered at the	6 033		

Texas Health and Human Services Commission

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
S 033	Continued From page 9 facility; (D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph; (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of Chapter 228 of this title (relating to Retail Food); (G) provide clean hand washing facilities for patients and staff including running water, and soap; (H) have two functioning sinks and a functioning toilet; and (I) have equipment available to sterilize instruments, equipment, and supplies in accordance with §139.49(d) of this title (relating to Infection Control Standards) before use in the facility. (2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action in facilities that provide vacuum aspiration.	S 033		

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	10/15/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 033	Continued From page 10 (3) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction shall minimize disruptions of existing functions. Access, exit ways, and fire protection shall be maintained so that the safety of the occupants shall not be jeopardized during construction. This Requirement is not met as evidenced by: Based on tour and interview, the facility failed to ensure a safe and sanitary environment, properly maintained to protect the health and safety of patients and staff at all times. Findings included: During a tour of the facility on 10/15/18, it was observed that there was large water stain approximately 3 feet X 10 inches in size observed on the ceiling of the recovery room. The presence of a water stain presents the risk for bacteria growth and contamination. The an interview with staff member # 1 on 10/15/18 they confirmed the above findings, stating the leak had been repaired previously by the facility, but that the building owner had not repaired the roof outside the building and the leak continued to be an issue.	6 033	6 033 • The Clinic Manager is responsible for ensuring the physical and environmental safety for all patients that come to WWHA. • The Clinic Maneger is responsible for contracting a vendor to assess interior ceiling to assess the risk for bacteria growth and contamination. The clinic manager has contacted the property owner regarding the need for an evaluation of the exterior roof. • The Clinic Manager contacted the property owner on 05/10/2018 and again on 06/15/18 to provide notice that the exterior roof needs to be evaluated. • The clinic manager contacted a vendor to assess the interior ceiling on 11/15/2018 who came out for evaluation on11/16/18. Upon evaluation, it was discovered that	
6 041	TAC 139.56 Emergency Services (a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital.	6 041		

			the external structure needed to be repaired and the Internal structure needed cosmetic repairs. The contractor is unable to complete Internal cosmetic repair and has referred to another company. The landlord was notified regarding repairs needed. Repairs to be determined pending contractor availability • In order to monitor continued compliance, the Clinic Manager will communicate with the property owner every 30 days regarding the progress of obtaining quotes, assessment, and or repair if needed of the exterior roof. • Currently in progress as of November 18,2018	

Texas Health and Human Services Commission

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S 041	Continued From page 11 The facility shall ensure that the physicians who practice at the facility: (1) have active admitting privileges at a hospital that provides obstetrical or gynecological health care services and is located not further than 30 miles from the abortion facility; (2) provide the pregnant woman with: (A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion; and (B) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. (b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services). (c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.	S 041		

Texas Health and Human Services Commission

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6 041	Continued From page 12 This Requirement is not met as evidenced by: Based on a review of documentation and staff interview, the licensee failed to provide a patient with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. Findings include: In 1 (patient #3) out of 20 clinical records reviewed the patients residence was listed in Houston, Texas and the facility provided the patient with the name and telephone number to a hospital located in Austin, Texas. The information provided to the patient was not the nearest hospital to the home of the patient's residence. The above was confirmed in an interview with the Director of Clinical Services on the evening of 10-15-2018.	6 041	6 041 • The Clinic Manager is responsible for ensuring compliance with all policies regarding medical and clinical services. • WWHA complies with the requirement that patients shall be provided with the name and telephone number of both the nearest hospital to her physical location and hospital nearest to where the patient might be residing during her recovery time. • An in-service was conducted with all staff on 10/18/2018 to review WWHA policy for Management of Medical Abortion and documentation of hospital nearest to the patient's physical residence during recovery. • In order to monitor compliance, the Clinic Manager will complete a monthly chart audit.	10/18/18
6 045	TAC 139.60 Other State and Federal Compliance Requiremen (a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs. (b) A licensed abortion facility that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all facilities with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the	6 045		

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	140013	A. BUILDING: _____ B. WING _____	10/15/2018

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WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

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6 045	Continued From page 13	6 045		

assessment of the health of, human beings.

(c) A licensed abortion facility shall ensure that its physicians comply with the Medical Practice Act, Occupations Code, Chapters 151 - 160 and 162 - 165, while functioning in his or her capacity at or for the facility.

(d) A licensed abortion facility utilizing the services of a physician assistant(s) shall ensure that its physician assistants comply with the Physician Assistant Licensing Act, Occupations Code, Chapter 204, while functioning in his or her capacity at or for the facility.

(e) A licensed abortion facility utilizing the services of a registered nurse shall ensure that its registered nurses comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility.

(f) A licensed abortion facility utilizing the services of a licensed vocational nurse(s) shall ensure that its vocational nurse(s) comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility.

(g) A licensed abortion facility that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Occupations Code, Chapters 551 - 569.

(h) A licensed abortion facility shall comply with the following federal Occupational Safety and Health Administration requirements:

(1) 29 Code of Federal Regulations, Subpart E,

Texas Health and Human Services Commission

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S 045	Continued From page 14 §1910.38, concerning emergency action plan and §1910.39, concerning fire prevention plans; (2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment; (3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection; (4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection; (5) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid; (6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers; (7) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning bloodborne pathogens; and (8) 29 Code of Federal Regulations, Subpart Z, §1910.1200, Appendices A - E, concerning hazard communication (hazardous use of chemicals). (i) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431. 111. Misbranded drugs or devices are described in Health and Safety Code, §431.112. (j) A licensed abortion facility shall not commit a	S 045		

Texas Health and Human Services Commission

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S 045	Continued From page 16 false, misleading, or deceptive act or practice as that term is defined in the Deceptive Trade Practices-Consumer Protection Act, Business and Commerce Code, §17.46. (k) A licensed abortion facility shall comply with the requirements of the Family Code, §33.002, relating to e Consent Form. (l) A licensed abortion facility shall comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act. (m) A licensed abortion facility shall comply with the requirements of Occupations Code, Chapter 102, Solicitation of Patients. This Requirement is not met as evidenced by: The facility failed to comply with the requirements of Health and Safety Code, Chapter 171. HEALTH AND SAFETY CODE, TITLE 2. HEALTH, SUBTITLE H. PUBLIC HEALTH PROVISIONS, CHAPTER 171. ABORTION, SUBCHAPTER A. GENERAL PROVISIONS stated in part, "Sec. 171.012. VOLUNTARY AND INFORMED CONSENT. (a) Consent to an abortion is voluntary and informed only if:.. 4) before any sedative or anesthesia is administered to the pregnant woman and at least 24 hours before the abortion or at least two hours before the abortion if the pregnant woman waives this requirement by certifying that she currently lives 100 miles or more from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility that performs more than 50 abortions in any 12-month period..."	S 045		

Texas Health and Human Services Commission

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S 045	Continued From page 16	S 045		

Based on a review of documentation and interview, the facility failed to ensure that A physician must perform a sonogram on a woman seeking an abortion at least 24 hours prior to performing the abortion, unless the woman lives 100 miles from the closest abortion provider in which case the sonogram must be performed at least 2 hours prior to the abortion.

Findings included:

Review of the medical record for Patient #7 revealed this patient lived less than 100 miles from the closest abortion provider. Patient # 7's sonogram displayed a date and time of 06/16/18 at 12:00 PM and the medical abortion procedure was initiated on 06/16/18 at 12:38 PM. This does not meet the 24 hour requirement of the sonogram being performed prior to the procedure.

In an interview on 10/15/18 staff member #2 stated it was possible that the sonography machine was recording the wrong time and/or date on the date in question. The staff member was not able to provide any documentation that the sonography machine was not working properly on this date.

During a tour of the facility on 10/15/18 at 3:40 PM it was observed that in Room #2 the sonography machine displayed a date of 10/16/18 and time of 03:40 PM. The date was incorrect the time was correct. Staff member #2 adjusted the date on the machine on 10/15/18 after this issue was noted during the tour to the correct date of 10/15/18.

Review of medical records for patient #1 revealed

Texas Health and Human Services Commission

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6 045	Continued From page 17 the patient listed two different places of residence on her peperwork. Petients medical history listed her residence es Houston, Texas and her Texas DSHS Sonogram and Abortion Election Form listed her residence as Plano, Texas. The facility used a USA Passport from the patient as their documented form of identificetion. A pessport does not contain a place of residence; therefore, no determination could be made if the patient actually lived at least 100 miles from the closest abortion facility. The above findings were confirmed on 10/15/18 in an interview with staff members #1 end 2.	6 045	6 045 • The Clinic Manager is responsible for ensuring the maintenance and accuracy of the ultrasound machine used to perform an ultresound. • WWHA compiles with ensuring that a physician preforms a sonogram on a patient seeking an abortion at least 24 hours prior to initiating the abortion. • After observing that the ultrasound machine is displaying and inaccurate date and time the sonographer changed the date and time. The same ultrasound machine continues to change to inaccurate dates and times. • The Clinic Manager had a service call placed on 06/19/2018 with a request for inspection and service of ultrasound. • In order to monitor compliance, Sonographer will verify time end date accuracy on a daily basis at the beginning of the day, and the Clinic Manager will do e monthly chart audit. • The clinic manager is responsible for obtaining documentation or self-certification of age, identity, and address for patients requesting an abortion. • Staff was re-trained on 10/18/2018 that a petient may provide self-certificetion of their current residence by completing the "Texas DSHS Sonogram and Abortion Election Form". Staff is	10/18/18

accountable to verify that the self-certified residence provided on the "Texas DSHS Sonogram and Abortion Election Form" is 100 miles or more from any abortion provider. Staff will verify the patient's attestation of her current residence by confirming that the patient has signed the required "Texas DSHS Sonogram and Abortion Election Form".

- In order to monitor compliance, the clinic manager will review all patient self-certification of residency on the "Texas DSHS Sonogram and Abortion Election Form" for each patient seeking to waive the 24 hour requirement prior to abortion procedure.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	49D2038942	A. BUILDING _____ B. WING _____	04/03/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS An announced CLIA recertification survey was conducted at Whole Women's Health of Charlottesville on April 3, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:	D 000		
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for three (3) of six (6) events reviewed. Findings include:	D2015	Documentation and Archival of Proficiency Tests and Attestations Systemic Changes: Whole Woman's Health (WWH) laboratory license holder since 2017, will be conducting an in-service with the staff on May 9, 2018 to review its policy for the document management of proficiency tests and attestations. As a result of the inspection, the clinic staff has organized the proficiency test results and attestations forms from the past two years into one centralized binder. This process ensures that the staff and the Labortory Director are compliant with Whole Woman's Health's policy for proper document management of proficiency tests. Oversight/Monitor: Under WWH's laboratory policies and procedures, the Laboratory Director and Clinic Director are responsible for conducting and documenting quarterly reviews for laboratory procedures. As of May 1, 2018, the Quarterly Site reviews will now require both parties to record the proper document management of proficiency test results and attestation on their submitted Quarterly Site Report. The WWH Quarterly Site Report is an internal mechanism to track clinic compliance with WWH policies and procedures.	May 9,2018

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: CoD | (X6) DATE: 4.24.18

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

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D2015	Continued From page 1 1. Review of the laboratory's 2016 American Academy of Family Physicians (AAFP) Blood Bank Testing Rh Factor PT documentation, and 2017 American Association of Bioanalysts (AAB), a total of six (6) events, revealed no signed attestation statements for: 2016 AAFP Event A, 2016 AAFP Event B, 2016 AAFP Event C. The inspector requested to review the attestation documentation. No documentation was available for review. 2. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory failed to retain copies of the AAFP attestation statements for the PT events outlined above in 2016.	D2015	Patient Look Back: Since this did not involve patient specimens and/or results, we determined that a patient look back is not required. Other Patient Tests: The Rh testing is the only moderately-waived CLIA test conducted by the clinic staff. The other two tests, urine pregnancy tests and hemoglobin, are CLIA waived and therefore not effected by this deficiency.	
D5215 510M	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to	D5215	Evaluation of Non-Graded Proficiency Tests Systemic Changes: Whole Woman's Health will be conducting an in-service with the staff on May 9, 2018 to review its policies and procedures for laboratory procedures. Specifically, the management of non-graded proficiency test results will be covered during the in-service. WWH's management as updated its laboratory service policies and procedures to state that if a non-graded response is received, the Laboratory Director will review the results of the samples with the analyst who conducted the proficiency tests and document the event in our Unsuccessful Proficiency Test Plan of Correction Form. (See attached policy)	May 9,2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5215	Continued From page 2 evaluate non-graded PT results for three (3) of fifteen (15) Blood Bank Testing Rh Factor challenges reviewed for calender year 2016. Findings Include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) PT documentation for 2016, a total of three (3) events and fifteen (15) challenges, revealed no evaluation or verification of accuracy for the non-graded responses for: 2016 Event C Blood Bank Testing Rh Factor - BB 11, BB 12, BB 13. The Inspector requested to review evaluation documentation for the three (3) non-graded challenges listed above. No additional documentation was available for review. 2. In an interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory failed to evaluate the non-graded PT results for the event listed above.	D5215	Oversight/Monitor: The Lab Director is responsible for the oversight and monitoring of any non-graded proficiency test results. As a part of the Quarterly Site review, the Laboratory Director will document their review of any non-graded results in the Quarterly Site Report and in the Unsuccessful Proficiency Test Plan of Correction Form. Patient Look Back: Since this did not involve patient specimens and/or results, we determined that a patient look back is not required. Other Patient Tests: The Rh testing is the only moderately-waived CLIA test conducted by the clinic staff. The other two tests, urine pregnancy tests and hemoglobin, are CLIA waived and therefore not affected by this deficiency.	
D5449 510M	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative	D5449	Quality Control Tests for Anti-D Rh Tests Systemic Changes: This was a variance from Whole Woman's Health established policies and procedures. The first implemented change to correct this deficiency will be an in-service held on May 9, 2018, for all laboratory staff on the proper method for quality control testing for Anti-D Rh tests. The current WWH policies and procedures reflect the correct quality control testing procedure, so no further policy changes will be made. In the interim, the Clinic Director will conduct daily verifications that Anti-D controls were appropriately performed.	May 9,2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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	49D2038942	A. BUILDING _____ B. WING _____	04/03/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5449	Continued From page 3 and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's test logs, quality assurance (QA) policy, and interviews, the laboratory failed to document quality control (QC) for Anti-D Rh tests on twenty (20) days of patient testing in the fifteen (15) months reviewed. Findings include: 1. During a tour of the laboratory testing area, the inspector noted the moderate complexity qualitative Eldoncard Rhesus Factor kits in use for RhD antigen detection. The inspector requested to see the quality control media used for the kits. The lab director stated "the QC is on order. We do not have any vials at this time". 2. Review of the laboratory's patient test logs from January 2016 to the date of the survey, April 3, 2018 revealed the following twenty (20) days with no QC documentation: 11/16/17, 12/13/17, 12/14/17, 12/20/17, 12/21/17, 01/03/18, 01/04/18, 01/10/18, 01/11/18, 01/18/18, 01/22/18, 01/23/18, 01/25/18, 01/30/18, 01/31/18, 02/01/18, 02/05/18, 02/06/18, 02/07/18, and 02/12/18. The inspector requested to review the QC documentation on the dates of patient testing listed above. No documentation was available for review.	D5449	Oversight/Monitor: The Clinic Director is responsible for the delivery of the in-service and oversight and monitoring of appropriate quality control testing. Starting April 18, 2018, daily monitoring of the lab log will occur for 30 days and will be documented in the laboratory log. This daily monitoring is an addition to policies and procedures because of this variation. If the corrective action is not working a follow-up in-service will be delivered and the daily monitoring will be extended for an additional 60 days. Patient Look Back: Between November 2017 and February 2018, there were 20 days of laboratory services, 50 patients received Rh screening tests. Starting the week of April 24th, 2018, we will randomly select 5% of the patients seen and bring them back for testing to confirm their Rh status. Other Patient Tests: Other patient tests were not affected by this deficiency as the only other tests provided by the clinic are CLIA-waived urine pregnancy and hemoglobin tests.	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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D5449	Continued From page 4 3. Review of the laboratory's QA policies revealed a QC protocol that stated: "Rh controls are to be documented daily. Results of all tests are recorded on the daily log sheet with proper laboratory testing protocol that QC is verified". 4. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory failed to document quality control (QC) for Anti-D Rh on twenty (20) days of patient testing in the fifteen (15) months reviewed.	D5449		
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must– (e)(4)(ii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, and an interview, the laboratory director failed to document evaluation of three (3) of six (6) Blood Bank Rh Factor PT modules reviewed.	D6018	Laboratory Director Systemic Changes: On April 20th the COO of Whole Woman's Health met with the Lab Director to review the Laboratory Director's roles and responsibilities. As part of that review, Whole Woman's Health established new processes for the Laboratory Director, who going forward effective May 1 will submit a quarterly reports documenting •Proper review and documentation of proficiency testing reports Oversight/Monitor: The direct line of supervision of the Laboratory Director has been changed. Going forward, the Laboratory Director will report to the Medical Director and Director of Clinical Services. The Laboratory Director reports referenced above will be submitted directly to the Director of Clinical Services. Patient Look Back: Since this did not involve patient specimens and/or results, we determined that a patient look back is not required.	April 20, 2018

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D6018	Continued From page 5 Findings include: 1. The inspector reviewed three (3) American Academy of Family Medicine (AAFP) PT events documents for 2016 and three (3) American Association of Bioanalysts (AAB) PT events for 2017. The PT review, a total of six (6) events, revealed no documentation of result evaluation for the following: 2016 AAFP Event B, 2016 AAFP Event C, 2017 AAB 1st Event. The inspector requested to review documentation of laboratory director review for the events. No documentation was available for review. 2. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was confirmed that the laboratory director failed document review for the proficiency testing events listed above.	D6018	-Other Patients: The Rh testing is the only moderately-waived CLIA test conducted in our clinic. The other two tests, urine pregnancy tests and hemoglobin, are CLIA waived and therefore not affected by this deficiency.	
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality	D6020		

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D6020	Continued From page 6 of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of patient test logs, procedure and policy manuals, and interview, the laboratory director failed to ensure that the QC policies were maintained for Anti-D Rh on twenty (20) days of patient testing in the fifteen (15) months reviewed. Findings include: 1. Review of the laboratory's patient test logs from January 2016 to the date of the survey, April 3, 2018 revealed the following twenty (20) days with no QC documentation: 11/16/17, 12/13/17, 12/14/17, 12/20/17, 12/21/17, 01/03/18, 01/04/18, 01/10/18, 01/11/18, 01/18/18, 01/22/18, 01/23/18, 01/25/18, 01/30/18, 01/31/18, 02/01/18, 02/05/18, 02/06/18, 02/07/18, and 02/12/18. The inspector requested to review the QC documentation on the dates of patient testing listed above. No documentation was available for review. 2. Review of the laboratory's QA policies revealed a QC protocol that stated "Rh controls are to be documented daily. Results of all tests are recorded on the daily log sheet with proper laboratory testing protocol that QC is verified". 3. During the exit interview with the Laboratory Director, Clinic Manager, and Director of Special Projects at approximately 4:30 PM, it was	D6020	Laboratory Director Systemic Changes: On April 20th the COO of Whole Woman's Health met with the Lab Director to review the Laboratory Director's roles and responsibilities. As part of that review, Whole Woman's Health established new processes for the Laboratory Director, who going forward effective May 1, 2018 will submit a quarterly reports documenting o Established and maintained quality control programs Oversight/Monitor: The direct line of supervision of the Laboratory Director has been changed. Going forward, the Lab Director will report to the Medical Director and Director of Clinical Services. The Laboratory Director reports referenced above will be submitted directly to the Director of Clinical Services. Patient Look Back: Between November 2017- February 2018, there were 20 days of laboratory services, 50 patients received Rh screening tests. Starting the week of April 24th, 2018, we will randomly select 5% of the patients seen and bring them back for testing to confirm their Rh status. Other Patients: The Rh testing is the only moderately-waived CLIA test conducted in our clinic. The other two tests, urine pregnancy tests and hemoglobin, are CLIA waived and therefore not affected by this deficiency.	April 20,2018

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D6020	Continued From page 7 confirmed that the laboratory director failed to ensure that the QC policies were maintained for Anti-D Rh on the twenty (20) days of patient testing listed above.	D6020		

Whole Woman's Health

Proficiency Testing
Non-Graded Results

Policy Statement

Whole Woman's Health participants in proficiency testing for our Moderate-Waived testing. The proficiency organization uses codes that signify that the proficiency test (PT) for an analyte has not been graded. Our laboratories must identify all of the analytes with an ungraded code and investigate the acceptability of performance.

Purpose of Policy

Assure consistent and proper functioning/verification of all clinical laboratory diagnostic procedures and analyses based on results obtained in assaying commercial unknown samples.

Procedure

1. Initial review of proficiency results may be performed by the Laboratory Director or Clinic Director.
2. The Laboratory Director will initial the individual findings/notations, review results, and sign entire report.
3. If ungraded exception code is present, the all participant statistics are reviewed for any explanation. Investigation of the following codes include, but are not limited to:

Reason Description	Action Required
Unable to Analyze	Documentation as to why not analyzed, (i.e., instrument not functioning or reagents not available.) Perform/document alternative proficiency test for the period that commercial PT was not tested.
Specimen Problem	Document that the laboratory has reviewed the proper statistics supplied by the Participant Summary. Perform and document alternative assessment for the period that the commercial PT was not tested to the same level and extent that would have been tested.
Result is outside the method/instrument reportable range	Documentation of the comparison of results to the proper statistics supplied in the Participant Summary.
No appropriate target/response; cannot be graded	Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, all method, or all results statistics if provided. If comparison is not available, perform and document alternative assessment (i.e. slit samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
Incorrect response due to failure to provide a valid response code	Document the laboratory's self-evaluation against the proper statistics and evaluation criteria supplied in the Participant Summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
Results from kit nor received and Results for this kit were received past the evaluation cut-off date.	Documentation why results were not received, corrective action to prevent recurrence, and the laboratory's self-evaluation of the results to the all participant statistics supplied by the Participant Summary. If PT specimens

	were not analyzed, perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested.
No Credit assigned due to absence of response	The Participant Summary indicates which tests are graded and which tests are not evaluated/educational. Updated to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result blank. However, if a test is graded (regulated analytes) and the laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for all challenges with in that test not performed/not applicable/not indicated. Exceptions may be noted in the kit instructions and/or the result form. Document corrective actions to prevent future failures.

State of Virginia

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	AF-0020	A. BUILDING _____ B. WING _____	06/07/2018

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T 000	Initial Comments An unannounced First Trimester Abortion Facility (FTAF) Biennial Licensure Inspection was conducted June 4, 2018, June 5, 2018 and June 7, 2018. Two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the Inspection. The inspectors conducted observations, interviews and document reviews to determine compliance. The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Rev. 03/22/2017). The deficiencies cited follow in this report.	T 000	Over a three day period between June 4, 2018, June 5, 2018, and June 7, 2018, inspectors from the Office of Licensure and Certification inspected Whole Woman's Health of Charlottesville. Nothing identified and described as "deficiencies" in the inspection report compromised patient health or abortion care. This Plan of Correction is provided to maintain Whole Woman's Health of Charlottesville's licensure and is not an admission by Whole Woman's Health of Charlottesville that the requirement to submit a Plan of Correction to the Virginia Department of Health in any way benefits patient health, or that any of the "deficiencies" described in the inspection report are valid. The leadership team of Whole Woman's Health of Charlottesville is responsible for the operation of the facility, including compliance with Virginia state regulations. Please see the specific plan of correction for each alleged deficiency under the appropriate tag below. The Clinic Director and Medical Director of Whole Woman's Health of Charlottesville are responsible for ensuring the implementetion of this plan of correction.	
T 045	12 VAC5-412-170 A Administrator The governing body shall select an administrator who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility including but not limited to: 1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights; 2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation; 3. Ensuring the accuracy of public information materials and activities; 4. Ensuring an effective budgeting and accounting system is implemented; and 5. Maintaining compliance with applicable laws and regulations and implementing corrective action.	T 045		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: CCC | (X6) DATE: 9/17/18

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T 045	Continued From Page 1 This RULE: is not met as evidenced by: Based on interview and document review it was determined the administrator failed to ensure nursing staff administered medication in compliance with physician orders for three (3) of four (4) patients that received oral sedation. (Patients #1, #10, and #11) The findings included: During an interview on June 4, 2018 at approximately 11:30 a.m., Staff Member #4 reported the facility's Administrator was away and would not return until June 7, 2018. Staff Member #4 reported he/she was the alternate Administrator. Staff Member #4 reported the facility utilized standing physician orders. Review of the facility's "Standing Orders for Surgical Abortions" included under "Sedation Options" "If a patient request oral sedation she may receive the following 0.5 mg (milligram) Diazepam (Valium) Or 0.5 mg Alprazolam (Xanax) ..." Review of Patient #1's medical record documented the patient was admitted and terminated her pregnancy on April 10, 2018. Patient #1's medical record documented the nurse administered "Xanax 1 mg." Review of Patient #10's medical record documented the patient was admitted on April 6, 2018 and terminated her pregnancy on April 10, 2018. Patient #10's medical record documented the nurse administered "Xanax 1 mg." Review of Patient #11's medical record	T 045	12 VAC5-412-170. Based on a document review and interview, the inspector determined that the standing orders did not reflect the dosages in practices for diazepam and alprazolam. The Medical Director and Clinic Director reviewed the Standing Orders for Whole Woman's Health of Charlottesville. Physician Standing Orders were updated 06/2018 to reflect the current practice of both physicians attending patients at Whole Woman's Health of Charlottesville. Dosages for diazepam and alprazolam were both updated as follows: "If a patient request oral sedation she may receive the following: 0.5-2 mg Diazepam *Or* 0.5-2 mg Alprazolam" The Medical and Clinic Directors will include a review of appropriate dosage as part of weekly chart audits. These audits will ensure that the Standing Orders for Whole Woman's Health of Charlottesville are updated and clarified, as needed.	

State of Virginia

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T 045	Continued From Page 2 documented the patient was admitted on March 15, 2018 and terminated her pregnancy on March 22, 2018. Patient #11's medical record documented the nurse administered "Xanax 1 mg." Interview and medical record reviews were conducted on June 6, 2018 from 3:36 p.m. though 3:47 p.m., with Staff Members #4 and #5. Staff Member #5 reviewed each medical record with the surveyors. Staff Member #5 verified the "Standing Orders for Surgical Abortions" in the medical record for Patients #1, #10, and #11 authorized the nurse to administer Xanax (Alprazolam) "0.5 mg." Steff Member #5 verified the medical records for Patients #1, #10, and #11 documented they were administered Xanax 1 mg without a physician's order. Staff Member #5 verified a nurse's scope of practice included administering medication in accord with the physician's order.	T 046		
T 195	12 VAC5-412-220 B Infection Prevention Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions;	T 195		

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T 195	Continued From Page 3 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on observation, interview and document review the facility failed to develop safe injection practices policies and procedures to protect patients and medical staff. The findings included: On June 07, 2018 at 11:30 a.m., surveyors observed Staff Member #7 during the preparation of intravenous medication for two patients. Staff Member #7 removed the top cover from a single dose vial of Fentanyl packaged as 100 mcg in 2 ml. Staff Member #7 did not wipe the septum with an alcohol wipe prior to piercing with a sterile needle attached to a syringe. Staff Member #7 then pulled the entire 2 ml solution into the syringe and removed the needle from the septum. Staff Member #7 then took a second sterile syringe that did not have a needle attached and placed the needle of the first syringe into the opening of the	T 195	12 VAC5-412-220. Based on document review and observation, the inspector found that procedures for handling controlled medications did not include single dose vials. The policies "Procedure for Handling Controlled Medications" and "Medication Therapy Practices" were updated 06/2018 to reflect best practices for infection control procedures for single dose vials, including proper septum sterilization, and medication preparation using single dose vials. An in-service training and review for clinic staff was held 07/09/2018 by the Clinic Director to update staff on the policy changes regarding the proper procedure for preparing controlled medications. In-service training logs were added to all staff personnel files. The Clinic Director will monitor medication preparation and provide remediation in-services as needed.	

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T 195	Continued From Page 4 second syringe so medication could be transferred between the two syringes. Steff Member #7 then injected 1 ml of solution into the second syringe so that both syringes would contain 1 ml of Fentanyl or a dose of 50 mcg for each patient, namely turning the single dose vial into a multi-dose vial. Staff Member #7 then prepared a 2 mg dose of Midazolam for each patient by using a single dose vial for each. Staff Member #7 failed to wipe the rubber septum of both vials of Midazolam with an alcohol wipe prior to piercing with e sterile needle. Staff Member #7 recepped the needles used during the preparation of the drugs and placed all used items in a sharps container before leaving the station. On June 07, 2018 at 12:21 surveyors discussed the medication preperation observation with Staff Member #5 end reviewed the clinic's policy end procedure. Although Staff Member #5 could identify e list of sources used as a basis for the clinic's policy and procedures es a whole, he/she could not apecifically identify the nationally recognized standard used as e source for the policy and procedure relating to the preparation of IV medication. Staff Member #5 further advised "my silence is egreement." Staff Member #7 provided a copy of two policies and procedures relating to the preparation of IV medication. Both policies specifically describe the preparation of medication from a multi-dose vial but neither policy and procedure outlined the preparation of medication from a single dose vial. The policies titled "Procedure for Handling Controlled Medications" and "Medication Therapy Practices" state in part: "If using the multi-dose vials, staff will clean the stopper of the MDV before each needle puncture."	T 195		

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T 195	Continued From Page 5	T 195		

Neither policy addresses the puncture of the stopper on a single dose vial.

The policy titled "Medication Therapy Practices" states in part:

"5. Staff will use a clean syringe and needle for each medication. For example, if the physician has ordered the staff to prepare IV sedation medications for 5 patients, the staff will...

d. Draw up 10 cc of Midazolam (10 mg/ 10 ml) into a syringe.
e. From that syringe, inject 2 cc (2 mg) each into 5 syringes..."

Staff Member #7 generally followed the policy and procedure as outlined by the clinic when preparing Fentanyl for two patients although it should be noted that neither policy or procedure specifically discussed single does vials.

According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "... IV.H. Safe Injection Practices
The following recommendations apply to the use of needles, cannulas that replace needles, and, where applicable, intravenous delivery systems:
... IV.H.5. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use ... CDC guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. ... Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile

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WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

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T 195	Continued From Page 6 environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it."	T 195	12 VAC5-412-220 The current "Policy for Infection Control" for Whole Woman's Health of Charlottesville was updated 08/2018 to reflect current best practices for infection control, including use and changing of linens. The updated policy was presented to staff by the Clinic Director during the monthly staff in-service on 08/23/2018. In-service training logs were added to all staff folders. The Clinic Director will monitor linen use and infection control and provide remediation in-services as needed.	
T 200	12 VAC5-412-220 C Infection Prevention Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (I) the level of cleaning/disinfection /sterilization	T 200		

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T 200	Continued From Page 7 to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines; 8. Procedures for appropriate disposal of non-reusable equipment; 9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations; 10. Procedures for cleaning of environmental surfaces with appropriate cleaning products; 11. An effective pest control program, managed in accordance with local health and environmental regulations; and 12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department. This RULE: Is not met as evidenced by: Based on observation, interviews, and document review it was determined the facility staff failed to ensure surfaces were disinfected between patients for one (1) of one (1) observation of cleaning post procedure. (Exam Room #2)	T 200		

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T 200	Continued From Page 8 The findings included: An observation was conducted on June 7, 2018 at 11:31 a.m., with Staff Member #6 during the cleaning/disinfection of Exam Room #2. Staff Member #6 removed the disposable paper from the exam table utilized during the termination of a pregnancy. Staff Member #6 used two (2) disinfectant wipes to clean and disinfect the surface of the exam table. Staff Member #6 cleaned in stages moving from the foot of the table to the head. On reaching the head of the exam table, Staff Member #6 picked up the pillow housed in a cloth pillow case. While holding the pillow in one hand, Staff Member #6 cleaned/disinfected the head portion of the exam table. After wetting the exam table with the disinfectant wipes, Staff Member #6 replaced the pillow on the exam table without changing the pillowcase. Staff Member #6 verbalized the exam table cleaning and disinfection was completed and started to pull up the disposable paper to cover the pillow and the rest of the exam table. The surveyor asked when the pillowcase would be changed. Staff Member #6 stated, "I change the pillow's case at the end of the day." Staff Member #6 verbalized understanding related to the need to change the cloth pillowcase between each patient's use of a pillow. At approximately 11:55 a.m. on June 7, 2018, the surveyor informed Staff Member #5 of the finding. Staff Member #5 verbalized the cloth pillowcases should be changed after each patient and placed in the dirty linen container.	T 200		

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T 260	Continued From Page 9	T 260	12 VAC5-412-240 Upon review of medical waste pickup schedules and documentation, the inspector found that medical waste was not picked up in the designated time frame. The "Regulated Medical Waste Disposal Policy" of Whole Woman's Health of Charlottesville was updated 08/2018 to: - reflect a maximum 15 day storage time as per Virginia state regulations - include additional efforts clinic management should make during periods of inclement weather or other extenuating circumstances to ensure pickup in the proper time-frame - proper documentation of these additional efforts (for example, email or phone logs to the medical waste vendor) The updated policy was presented to staff by the Clinic Director during the monthly staff in-service on 08/23/2018. In-service training logs were added to all staff personnel files. Vendor contract was updated and revised 08/2018 to add pickups every 14 days.	
T 260	12 VAC5-412-240 D Medical Testing and Laboratory Services All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120). This RULE: Is not met as evidenced by: Based on interview and document review it was determined facility staff failed to ensure the disposal of regulated medical waste, namely products of conception (POC), occurred within the required 14 days, for 6 out of eight 8 surgical procedures reviewed during the medical records assessment. The findings included: On June 5, 2018 at 9:32 a.m. during a tour of the room where POC is packaged and stored, Staff Member #6 advised the facility policy states medical waste can be stored in the medical waste refrigerator for up to two weeks. He/she further advised some items may have remained in the refrigerator for a month specifically the month before due to a significant rainstorm. On June 5, 2018, during a medical records review, surveyors found 8 surgical procedure dates that resulted in POC storage. On that same date, surveyors examined the medical waste pick-up log and cross-referenced the log finding the following POC storage where the medical waste remained at the facility for more than 14 days. e. On April 10, 2018, Patient #1 underwent a surgical procedure that resulted in POC. That	T 260		

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T 260	Continued From Page 10 medical waste remained at the facility for 20 days until picked-up on April 30, 2018. b. On April 10, 2018, Patient #4 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 20 days until picked-up on April 30, 2018. c. On April 10, 2018, Patient #10 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 20 days until picked-up on April 30, 2018. d. On April 12, 2018, Patient #8 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 18 days until picked-up on April 30, 2018. e. On May 1, 2018, Patient #5 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 34 days until picked-up on June 4, 2018. f. On May 3, 2018, Patient #2 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 32 days until picked-up on June 4, 2018. On June 05, 2018 at 4:11 p.m. surveyors reviewed the medical records and medical waste pick-up logs with Staff Member #4 and Staff Member #5 in relation to the disposal of medical waste. Staff Member #4 advised the policy for the clinic is to have medical waste removed from the facility within 14 days. Staff Member #4 further reviewed the Virginia regulation and advised the regulation provided for a 15 day storage period before removal. Staff Member #4 advised he/she does acknowledge the facility violated its policy. A review of the clinic's policy titled "Regulated Medical Waste Disposal Policy" states in part: "Storage of Biomedical/Biohazardous Waste shall not be greater than 14 days." According to 9VAC20-120-150 products of	T 268		

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T 260	Continued From Page 11 conception is considered regulated waste. "List of controlled regulated westes ... 3. Tissues and other anatomical wastes. All human anatomical wastes end all wastes that are human tissues, organs, or body parts are regulated medical waste ..." According to 9VAC20-120-360. "Temperature Control and Storage Period. Any regulated medicel waste stored for more than seven days must be refrigerated, stored in an embient temperature between 35° and 45°F (2° and 7°C). If the material is stored eway from the site of generation and the time in storege is unknown, the reguleted medical waste must be refrigerated. No regulated medical waste shall be stored for more than 15 days at the site of generation. Procedures shall be provided to ensure that the above storage timeframes are met. The date that the waste is first placed in storage will be provided on any outer packaging while the waste is in storage."	T 260		
T 280	12 VAC5-412-250 D Anesthesia Services An abortion facility administering moderate sedation/conscious sedation shall maintein the following equipment, supplies and pharmacological agents, as required by 18 VAC 85-20-360 B: 1. Appropriate equipment to manage airways; 2. Drugs and equipment to treat shock and anephylactic reactions; 3. Precordial stethoscope; 4. Pulse oximeter with eppropriate alerms or an equivalent method of measuring oxygen	T 280	12 VAC5-412-250 Upon inspection of clinic sedation management equipment the inspector determined there was no continuous electrocardiograph on site. Clinic management reviewed Whole Woman's Health of Charlottesville's equipment for proper moderate/ conscious sedation management 06/2018. It was determined that the AED on-site during the time of inspection (Zoll AED Plus) has the capability to continuously display ECG signals in real time. Further information is detailed in the Zoll AED Plus Administrator's Guide (attached) on page 9. The instructions were presented to staff by the Clinic Director during the monthly staff in-service on 07/09/2018. In-service training logs were added to all staff personnel files.	

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T 280	Continued From Page 12 saturation; 5. Continuous electrocardiogreph; 6. Devices for measuring blood pressure, heart rate and respiretory rate; 7. Defibrillator; and 8. Accepted method of identifying and preventing the interchangeability of gases. This RULE: is not met as evidenced by: Based on observation, interview and document review it was determined the facility failed to maintain equipment as required by 18VAC85-20-360 B for a facility administering moderate sedation/conscious sedation, namely a device for continuous electrocardiograph monitoring. The findings included: On June 4, 2018, at 4:15 p.m. with Staff Member #5 and Staff Member #7, surveyors examined clinic equipment, supplies and pharmacological agents to determine if they were present and in good working order to satisfy the regulation for facilities administering moderate sedation/conscious sedation. During that examination, surveyors could not locate equipment capable of continuous electrocardiograph monitoring. Staff Member #5 and Staff Member #7 confirmed the clinic did not have the equipment onsite to satisfy that requirement. On June 5, 2018, a surveyor review of privileging documents for Staff Member #2 and Staff Member	T 280		

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T 280	Continued From Page 13 #3 revealed procedure privileges that included conscious sedation. Additionally, on that same date, medical records review revealed patient records that included a signed consent for conscious sedation and documentation of conscious sedation used during procedures. On June 07, 2018 at 10:10 a.m. during an interview with Staff Member #5, he/she revealed the clinic performed 37 procedures utilizing conscious sedation since March 01, 2018. Additionally, at 1:12 p.m., Staff Member #4 advised two (2) conscious sedation procedures were scheduled on this date and a device for continuous electrocardiograph monitoring was not in place after the realization of the deficient practice three days prior. A review of the clinic's policy and procedures titled "Anesthesia Services states in part: "THE CLINIC offers Office Based conscious sedation, and local anesthesia services, directed and under the supervision of a Virginia licensed physician who is certified in ACLS... The following supplies and equipment are readily available on site ... 5. Continuous electrocardiograph ..."	T 280		
T 315	12 VAC6-412-260 C Administration, Storage, Dispensing of Drugs Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10.	T 315		

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T 315	Continued From Page 14 This RULE: is not met as evidenced by: Based on observations, interviews and document reviews it was determined the clinical staff failed to ensure: 1. Controlled medication withdrawn from its vial was stored with a label that identified the amount, strength, and date, with the initials of the clinician that placed the medication in the syringe or discarded. 2. Expired medications were not available for administration. The findings included: 1. Observations during the initial tour of the facility on June 4, 2018 at 1:00 p.m., with Staff Members #4 and #5 revealed a syringe of clear liquid within the controlled medication lock box. The syringe on inspection had a partially attached blue label with the printed word "Fentanyl." The label did not identify the amount, strength, date or who removed the medication from its vial. The label also did not include a patient's name. An interview was conducted on June 4, 2018 at approximately 1:09 p.m., with Staff Members #4 and #5. Staff Member #5 verified the syringe was not stored according to the facility's policy. Staff Member #5 reported if the medication was been drawn to administer to a patient and the patient declined, the medication should have been wasted by two (2) licensed staff. The surveyor requested the facility's policy. Review of the facility's policy titled "Medication Therapy Practices" and the policy titled "Procedure for Handling Controlled Medications	T 315	12 VAC5-412-260 Upon inspection of on-site medications, the inspector determined expired medications were on site. An in-service training and review for staff for proper medication storage, disposel, and labeling was held by the Clinic Director 06/14/18. This in-service reviewed current policies and procedures for proper medication storage and disposal, including monitoring of expiration dates, proper labeling of medications, and proper medication wasting. Additional training was given on the newly implemented color-coded labeling system to monitor madication expiration dates. In-service training logs were added to all staff personnel files. New staff will be trained on proper storage, disposal, and labeling during orientation in order to prevent recurrence.	

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T 315	Continued From Page 15 contained the same wording. The policies read in part "Drawing up IV [Intravenous] Sedation ... 6. Each syringe drawn up will be labeled with the patient's name, medication quantities and strength, date and staff initials ..." Review of the facility's policy titled "Medication Therapy Practices" directed "Wasting Medications ... 2. Controlled medications: once a dose has been drawn and prepared for patient use, if the medication is not administered, a staff member will dispose of the syringe into a sharps container while another staff witnesses. You can drain the medication into the sharps container before throwing the syringe as well. Or you can simply throw the syringe into the container without draining it ..." An interview was conducted on June 5, 2018 at approximately 4:33 p.m., with Staff Members #4 and #5. Staff Members #4 and #5 verified two (2) licensed staff should have wasted the syringe/medication found in the controlled medication lock box. 2. An observation was conducted on June 4, 2018 at 1:37 p.m., in the facility's "Aftercare Area" with Staff Members #4 and #5. The observation revealed a medication refrigerator in the "Aftercare Area." Observation of the medications housed in the refrigerator included an opened vial of Tuberculin Purified 5 TU (tuberculin units)/0.1 mL (milliliter) 1 mL vial dated as opened on "11/14/17." Staff Member #4 verified the vial was approximately "half full." The surveyor inquired regarding the facility's policy for discarding multidose medication vials after opening. Staff Member #5 reported the medication was discarded twenty-eight (28) days after being opened. The surveyor requested Staff	T 315		

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T 315	Continued From Page 16 Member #4 to verify the date recorded on the Tuberculin Purified 5 TU/0.1 mL vial and the box. Staff Member #4 verbalized the date as "11/14/17." Staff Member #4 reported the licensed staff was responsible for ensuring all expired medications were properly discarded. Staff Member #5 stated, "It's over the limit. Don't place it back in the refrigerator. We need to discard it." The surveyor requested the facility's policy regarding when opened medication needed to be discarded. The surveyor requested the manufacture's directions included within the Tuberculin Purified 5 TU/0.1 mL box. Review of the manufacturer's directions "...Vials in use for more then 30 days should be discarded." Review of the facility's policy titled "Medication Therapy Practices," which read in part "Wasting Medications 1. All expired non-controlled medications should remain in the original bottle, and disposed into the Medical RX disposal container. This container will be removed from the facility by a specialized contracted company for proper disposal ..." During an interview on June 5, 2018 at approximately 4:35 p.m., Staff Members #4 and #5 verified the findings of the surveyor regarding the medications.	T 315		
T 355	12 VAC5-412-300 Health Information Records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. If medically indicated, it shall include, but not be limited to the following:	T 355		

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T 355	Continued From Page 17 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge, i. Patient instructions (preoperative and postoperative); j. Names of referral physicians or agencies; and 6. Any other information required by law to be maintained in the health information record. This RULE: is not met as evidenced by: Based on interviews and document review it was determined: 1. The licensed nursing staff failed to document patient progress notes for three (3) of nine (9) surgical abortion patients included in the inspection sample. (Patients #11, #1 and #10) 2. The discharging nurse failed to document the correct level of consciousness (LOC) in accord with the facility's scale, for five (5) of nine (9) surgical abortion patients included in the inspection sample (Patients #1, #2, #6, #8, #10 and #11)	T 355	12 VAC5-412-300 On inspection of patient charts inspectors found that the section on the patient's record labeled "progress notes" was sometimes left blank. Staff were instructed to indicate N/A if no notes were needed instead of leaving the section blank. An in-service for staff was held 08/23/2018 regarding the proper documentation of progress notes in patient charts. In-service training logs were added to staff personnel files. Clinic management determined that the training for documenting level of consciousness (LOC) was based on the Ramsay scale, however physicien standing orders for LOC did not reflect this scele, and used an older version (reference ettached). Standing orders were updated 06/2018 to accurately reflect the use of the Ramsay scale at Whole Woman's Health of Charlottesville. The Clinic Director will include e review of progress notes and LOC documentation as part of weekly chart audits.	

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T 355	Continued From Page 18 The findings include: 1. The facility's nurse providing after procedure care failed to document a patient progress note, leaving that section of the patient's medical form blank for Patient #11 on March 22, 2018, and for Patient #1 and Patient #10 on April 10, 2018. 2. The facility's "Standing Orders for Surgical Abortion;" includes the discharge criteria for surgical patients. The facility's standing orders indicates the patient could be discharge when their "LOC (level of consciousness) is 10." On April 10, 2018, the discharging nurse indicated Patient #1's LOC was "2" at discharge. On May 3, 2018, the discharging nurse indicated Patient #2's LOC was "2" at discharge. On April 28, 2018, the discharging nurse indicated Patient #6's LOC was "2" at discharge. On April 12, 2018, the discharging nurse indicated Patient #8's LOC was "2" at discharge. On April 10, 2018, the discharging nurse indicated Patient #10's LOC was "2" at discharge. On March 22, 2018, the discharging nurse indicated Patient #11's LOC was "2" at discharge. Interviews and patient chart reviews were conducted on June 5, 2018 from 3:38 p.m. through 4:03 p.m., with Staff Members #4 and #5. Staff Member #5 reviewed each patient medical record with the surveyors. Staff Member #5 verified each finding. Staff Member #5 stated, "[Name of Staff] works at a hospital, their scale must be different than the one we use" regarding the level of consciousness at the time of discharge. Staff Member #5 reported per the facility's scale for LOC at a level two (2) "the patient would not be able to walk." Staff Member #5 reported the surveyors' findings indicated the facility's medical records were inaccurate.	T 355		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0020	A. BUILDING _____ B. WING _____	06/07/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

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T 355	Continued From Page 19 Review of the facility's policy titled "Policy for Medical Records/Clinical Records" read in part "The Clinic will maintain clinical records in their original state. Each entry will be accurate, dated with the date of entry, and signed by the individual making the entry ..." With regard to medical record content the facility's policy titled "Policy for Medical Records/Clinical Records" specified the inclusion of progress notes.	T 355		

THE LAWYERING PROJECT

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Rupali Sharma
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January 25, 2019

Kristina Box, MD, FACOG
State Health Commissioner
Indiana State Department of Health
2 North Meridian Street
Indianapolis, Indiana 46204

Dear Dr. Box:

On behalf of Whole Woman's Health Alliance ("WWHA"), enclosed please find in support of WWHA's Application for a License to Operate an Abortion Clinic, submitted January 16, 2019, a recent inspection report concerning WWHA's Virginia clinic and the proposed Plan of Correction that WWHA submitted to the Virginia Health Department on January 18, 2019.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Rupali Sharma
Senior Counsel & Director

encs.

cc: Sharon Lau
Amy Hagstrom Miller
Katherine D. Jack
Dipti Singh
Stephanie Toti

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0020	A. BUILDING _____ B. WING _____	01/03/2019

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WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

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{T 000}	Initial Comments An unannounced Licensure Revisit Inspection to the Biennial Licensure Inspection which was completed on June 4 through June 5, 2018 and June 7, 2018, was conducted January 3, 2019, by two (2) Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. The facility was not in compliance with 12 VAC 5-412, Regulations for the Licensure of Abortion Facilities (Rev. 2017) in the area of Infection Prevention and for Administration, Storage and Dispensing of Drugs. Corrections are required. Other areas previously cited (Administration, Medical Testing and Laboratory Services, Anesthesia Services, and Health Information Records) were cleared.	{T 000}	The leadership team of Whole Woman's Health of Charlottesville is responsible for the operation of the facility, including compliance with Virginia state regulations. Please see the specific plan of correction for each alleged deficiency under the appropriate tag below. The Clinic Director and Medical Director of Whole Woman's Health of Charlottesville are responsible for ensuring the implementation of this plan of correction.	
{T 195}	12 VAC5-412-220 B Infection Prevention Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;	{T 195}	12 VAC5-412-220 B Infection Prevention The Clinic Director is responsible to ensure that staff follow Whole Woman's Health written policy and procedures. The Medical Director will complete a peer led training with a fellow Whole Woman's Health Medical Director on/before February 8, 2018 to review Whole Woman's Health Procedure for Handling Controlled Medications. Additionally, the Clinic Director will also complete an in-service conducted by Director of Clinical Services to review Procedure for Handling Controlled Medications. In order to monitor compliance, an internal audit clinic will be conducted during the clinic's next quarterly quality assurance survey. The Clinic Director will continue to monitor Controlled Medication counts daily.	March 1, 2019

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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{T 195}	Continued From Page 1 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: Is not met as evidenced by: Based on interview and document review, it was determined facility staff failed to ensure that single use vials were used one time for one patient only. Findings included: On January 3, 2019 at 2:30 p.m., an interview was conducted with Staff Member (SM) #2, related to carrying IV (intravenous) medications for sedation pre-drawn in a syringe in a fanny pack around his/her waist. SM #2 stated "I look at the schedule for the day, and draw up what I expect to use, place it in the fanny pack, which I keep on me the rest of the day. I use medications from the fanny pack as needed for sedation." SM #2 also stated, "Medications not used are discarded at the end of the day, and that is recorded in the log". The surveyor inspected the pre-drawn syringes,	{T 195}		

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{T 195}	Continued From Page 2 and noted that they were labeled with medication name, strength, lot number; however, did not include the date the medication was withdrawn from the vial, or the initials of the person drawing up the medication. SM #2 stated, "Some patients do not need the full dose of the medication, so I will draw up half e dose for them. I use the other half for another patient". The surveyor followed up, and esked SM #2 if he/she used medication from a single dose vial for more than one patient, end he/she stated, "Yes, sometimes, the patient doesn't need but half a dose, so I use the other half for enother patient". The surveyor reviewed the facility's policy entitled "Procedure for Handling Controlled Medications" with SM #2, specifically the section entitled "Drawing up IV Sedation", which stated in part the following: "5 ...Single-dose vials should be for single use only and used for one patient. SDVs [sic] are not to be used as MDVs [sic] under any circumstences. 6. Unless otherwise ordered by the physician, each patient will receive for sedation the medications ordered on the standing orders Nalbuphine 10 mg, Fentanyl 50 mcg-100 mcg Midazolam 1-2.5 mg ...8. Each syringe drawn up will be labeled with the medication quantities and strengths, dete, and staff initials. SM #2 stated, "I was not eware that I couldn't use the medication from the vial for more than one patient. I was trying to keep from wasting the medication". According to facility documentation, SM #2 had attended en inservice on 7/9/18 regarding the facility policy and procedure for this practice evidenced by the staff members signature on the sign-in sheet.	{T 195}		

State of Virginia

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{T 195}	Continued From Page 3 Concerns were discussed with SM #1, the Clinic Director, on 1/3/19 at 3:45 p.m., and with SM #2, the Medical Director, as noted above.	{T 195}		
{T 315}	12 VAC5-412-260 C Administration, Storage, Dispensing of Drugs Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10. This RULE: Is not met as evidenced by: Based on observation and staff interview, it was determined facility staff failed to ensure that medication syringes were labeled per the facility's policy and medication was stored per the manufacturer's recommendations. Findings included: On 1/3/19 at 2:30 p.m., an interview was conducted with Staff Member (SM) #2, the Medical Director, related to carrying IV (intravenous) medications for sedation pre drawn up in a syringe in a fanny pack around his/her waist. SM #2 stated "I look at the schedule for the day, and draw up what I expect to use, place it in the fanny pack, which I keep on me the rest of the day. I use medications from the fanny pack as needed for sedation". SM #2 also stated, "Medications not used are discarded at the end of the day, and that is recorded in the log." The surveyor inspected the pre-drawn syringes, and noted that they were labeled with medication name, strength, lot number; however, did not	{T 315}	12 VAC5-412-260 C Administration, Storage, Dispensing of Drugs The Clinic Director is responsible to ensure that staff follow Whole Woman's Health written policy and procedures. In order to ensure we continue to comply with manufacture recommendations, all Controlled Medications will remain in designated controlled secured area until the Medical Director will completes peer led training a fellow Whole Woman's Health Medical Director on/before February 8, 2018 to review Whole Woman's Health Procedure for Handling Controlled Medications. Additionally, the Clinic Director will complete an in-service conducted by Director of Clinical Services to review Procedure for Handling Controlled Medications. A temperature log documenting the room temperature where controlled medications will be completed daily by designated clinic staff. An in-service with all clinic staff led by the Clinic Director will be completed on or before February 8, 2019 to introduce new log. The Clinic Director will continue to inspect all controlled medications labels for accuracy and document on Controlled Medications Log on a daily basis .	February 8, 2019

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{T 316}	Continued From Page 4 Include the date the medication was withdrawn from the vial, or the initials of the person drawing up the medication. The facility's policy entitled "Procedure for Handling Controlled Medications", which stated in part the following: " ...8. Each syringe drawn up will be labeled with the medication quantities and strengths, date, and staff initials ..." The surveyor reviewed the policy with SM #2, who stated, "I did not know I was to include the date/initials on the label". The surveyor reviewed the FDA prescribing information for Fentanyl Citrate Injection USP, and noted the following information , in part under the heading "Storage" included the following information: "Store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F) [see USP Controlled Room Temperature). PROTECT FROM LIGHT.". According to facility documentation, SM #2 had attended an inservice on 7/9/18 regarding the facility policy and procedure for this practice evidenced by the staff members signature on the sign-in sheet. Concerns were discussed on 1/3/19 at 2:20 p.m. with SM's #2, Medical Director, and #3, the Medical Assistant, at the time of the observation, and with SM #1, the Clinic Director, on 1/3/19 at 3:45 p.m.	{T 316}		